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09/602,874	06/23/2000	Markus Pompejus	BGI-123CP	2764

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 02/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,874

Applicant(s)

POMPEJUS ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 11, mailed on October 16, 2002), Applicants filed an election and amendment received on November 25, 2002 (Paper No. 13). Said amendment cancelled Claims 1-24 and 35-38 and amended Claims 25, 27, and 34. Thus, Claims 25-34 are pending in the instant Office action and will be examined herein.

Election

2. Applicants' election without traverse of Group III, Claims 25-34, in Paper No. 13 is acknowledged. Applicants' election of the species "*Corynebacterium glutamicum*" and "lysine" without traverse is also noted.

Applicants' election of species "SEQ ID NO:1" *with traverse* is noted. The traversal is on the ground(s) that a reasonable number of sequences, "normally up to ten" can be examined together even when they are independent and distinct. This is not found persuasive for the following reasons. The MPEP states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction" (see M.P.E.P. § 803.04). That is to say that SEQ ID NOs: 1, 3, 5, 7, 9, 13, 15, 17, 19, and 21 could be examined together without undue burden. However, the instant claims are drawn to a **genus** of DNA (not just SEQ ID NO:1) by virtue of the 60% identity language, 30 nucleotide fragment language, encoding 10 contiguous amino acids, and protein encoding language. Particularly, any DNA which encodes the polypeptides (encoded by the above SEQ ID NOs), which polypeptides are SEQ ID NOs: 2,

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4, 6, 8, 10, 14, 16, 18, 20, and 22, is not included in this group; the search for a specific nucleic acid sequence is different from the search for all possible nucleic acid sequences encoding a particular protein, even if that protein is encoded by the original nucleic acid sequence. Thus, a complete search of the DNA is a search of not only the DNA that is SEQ ID NO:1, but also a search of other DNAs encoding SEQ ID NO:2 as well as all the DNAs within the variation (fragment, % identity) language. Moreover, these distinct genes encode distinct proteins and the MPEP states that "nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another" (see M.P.E.P. § 803.04).

Applicants also argue that a species election is more appropriate in this case. The Examiner disagrees. Species elections are only appropriate when a single, generic sequence, such as a consensus sequence, can be searched to effectively search the entire genus. That is not the case here.

Applicants also argue that a search with regard to each SEQ ID NO would be co-extensive with the others. The Examiner fails to see this logic without a disclosed consensus sequence or homology alignment; each SEQ ID NO would need to be searched and evaluated for its art separately.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. The instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031 filed on June 25, 1999, 60/142,690 filed on July 1, 1999, and 60/151,251 filed on August 27, 1999 as requested in the declaration and the first lines of the specification.

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The instant application is not granted the benefit of priority for the 12 foreign applications filed in Germany as requested in the declaration because the instant application does not comply with the rules set out in 35 U.S.C. § 119 (a)-(d): namely, the foreign application was filed more than 12 months before the U.S. filing date and/or a certified copy of the original foreign application has not been filed with the Office. Applicants are requested to comply with these rules, if possible, or withdraw claims to priority benefits.

Information Disclosure Statement

4. No information disclosure statement has been filed with the instant application as of the date mailed of the instant Office action. Applicants are reminded that they have a duty to disclose all information, of which they are aware, relevant to the patentability of the pending claims (see 37 C.F.R. § 1.56 and M.P.E.P. § 2000).

Objections to the Specification

5. The specification is objected to because the title is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new title:

---Methods of Producing a Fine Chemical Using a Glucose Resistance Amylase
Regulator protein from *Corynebacterium glutamicum*---

6. In the specification, the Abstract is objected to for containing the abbreviation "MR" without definition. This abbreviation would be wholly unclear without reading the description,

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which is not as universally available. Definition of the abbreviation in the specification is required.

7. The specification is objected to for being confusing on the following points:
 - a) On page 2, line 34, the term “e.g.” is listed with no examples following it.
 - b) In Table 4, the % homology is in the tens of thousands while percent is a range from 1-100.

Correction and/or clarification is required.

8. The specification is confusing in Table 1; the assignment of functionality is wholly unclear. For example, in Table 4, the assignment of function is clear. No sources or procedures are named for the sequences in Table 1. Explanation is required.

Claim Objections

9. Claim 29 is objected to for a typographical error. On page 2, the comma between *Corynebacterium* and *lilium* is inappropriate. Correction is required.

Claim Rejections - 35 U.S.C. § 112

10. Claim 29 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Several of the names are inappropriate members of the Markush group because they either are aliases or cannot be found in the art as a recognized species:

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- a) *Corynebacterium lilium* is an alias for *Corynebacterium glutamicum*
- b) *Corynebacterium acetophilum* is an unknown species
- c) *Brevibacterium ammoniagenes* is an alias for *Corynebacterium ammoniagenes*
- d) *Brevibacterium divaricatum* is an alias for *Corynebacterium glutamicum*
- e) *Brevibacterium flavum* is an alias for *Corynebacterium glutamicum*
- f) *Brevibacterium lactofermentum* is an alias for *Corynebacterium glutamicum*
- g) *Brevibacterium paraffinolyticum* is an unknown species.

Also, in Table 3, generic *Brevibacterium* species and *Corynebacterium* species are noted, but their definition is unclear. Clarification and/or correction is required.

11. Claim 31 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Markush member “enzymes” as a fine chemical is confusing. While amino acids can be considered fine chemicals, an assembly of amino acids into the form of a protein/enzyme is not considered a fine chemical. Such a definition is repugnant in the art. Correction is required.

12. Claim 34 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is confusing how the introduction of the complement of a coding sequence can effect the production of a fine chemical. The disclosure describes SEQ ID NO:1 as a coding sequence of a glucose resistance amylase regulator. It is unclear how the complement of this gene, when introduced into the genome of a host cell, could be productive.

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13. Claim 34 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "about" in claim 34 is a relative term, which renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 25-34 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to methods of using SEQ ID NO:1 or variations of said sequence.

SEQ ID NO:1 is 514 base pairs long with a defined coding sequence of 101-514; an unusual valine amino acid is described as the start codon and no stop codon is disclosed. The encoded amino acid, SEQ ID NO:2, is 138 amino acids long. SEQ ID NO:1 is described in Table 1 as a glucose resistance amylase regulator. No description, other than a name, is found in the instant specification. The art contains a single reference (Henkin *et al.*) relating the function of a glucose resistance amylase regulator and several GenBank references of sequences from

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various bacteria, all of which are greater than 340 amino acids in length. No alignment of SEQ ID NO:2 and art-defined glucose resistance amylase regulators can be found, but the homology is very low.

Although the species of glucose resistance amylase regulator SEQ ID NO:2 is discussed in the specification, there is no clear evidence that this sequence is a glucose resistance amylase regulator. No testing of activity is disclosed; no homology alignments are offered. Thus, without a clear function of the disclosed sequence, the characteristics of the sequence are inadequately described in the instant specification as originally filed. To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. In this case, item (1) is not met. If Applicants can convincingly demonstrate that SEQ ID NO:1 particularly encodes a glucose resistance amylase regulator, for example, by significant homology alignment, this portion of the rejection would be withdrawn.

In addition to the above written description issue, the instant claims are rejected based on their open claim language in the absence of the disclosure of full-length genes. The instant claims are drawn to methods using a nucleotide sequence *comprising* SEQ ID NO:1; the open claim language reads on the use of the full-length gene. SEQ ID NO:1 is not a full-length open reading frame based on the absence of a real start and stop codon and based on the small size of the encoded protein relative to other art. Insofar as the disclosed polynucleotide sequence

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directly encodes the entire functional portion of a glucose resistance amylase regulator, the instant specification provides adequate written description. However, it would be impossible for one of skill in the art to predict the polynucleotide sequences extending from the disclosed sequence to encompass the full-length gene containing of the disclosed sequence. This is not to say that applicants have not enabled one of skill in the art to obtain the full length gene sequence using well-known hybridization techniques; this is to say that applicants have not described, directly or predictably, the sequence of the full-length gene. Given the limited disclosure of structurally described species and the unpredictability of the art, applicants have failed to adequately describe a representative species of the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention, i.e., the full length gene.

In addition to the above written description issues, Claim 34 is also rejected based on its claiming the use of polynucleotides described by variable structure without function. The instant specification discloses polynucleotides with at least 60% with SEQ ID NO:1. Applicants have fully described the genus relating to said SEQ ID NOs with both sequence identity limitations and functional limitations (i.e., having glucose resistance amylase regulator, provided that this is a real function of the encoded polypeptide, as noted above). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

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Claim Rejections - 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

15. Claims 25-34 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either an asserted utility or a well-established utility. As noted above, the function of the encoded protein, glucose resistance amylase regulator, is not convincing given the disclosure. Without a known function, it is unclear how to use such a polynucleotide or such a method using a polynucleotide, i.e., what fine chemical to produce?

16. Claims 25-34 are also rejected under 35 U.S.C. § 112, first paragraph, enablement. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

17. Claims 25-34 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



KMK

February 6, 2003